REMARKS

Claims 1-9 are pending in the instant application. Claims 1-9 have been rejected. Claim 1 has been amended. Claim 2 has been canceled. No new matter has been added by this amendment. Reconsideration is respectfully requested in light of the following remarks.

I. Rejection of Claims Under 35 U.S.C. §112

The rejection of claims 1-9 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention have been maintained. Claims 1-9 are drawn to a method of stably expressing a selected DNA sequence in the central nervous system of a mammal. The Examiner suggests that the specification provides no use for mere stable expression other than for gene therapy. Further, the Examiner has suggested that the specification does not provide guidance for other vectors and promoters for use in methods of treatment where a prediction of success can be made. Applicants respectfully traverse this rejection.

Applicants respectfully disagree with the Examiner on the basis of enablement as it appears that most of the Examiner's comments focus on a reduction to practice. As set forth by MPEP 2164.01, proper analysis of whether a particular claim is supported by the disclosure in an application requires a

determination of whether that disclosure, when filed, contained sufficient information regarding the *subject matter of the claims* as to enable one skilled in the art to make and use the claimed invention. The present invention does not claim methods for treating a disease of the CNS, rather the *subject matter* of the instant claims relates to methods for stably expressing a selected DNA sequence in the central nervous system. In accordance with these claims, the specification sufficiently discloses each element of the claims including how to administer to peripheral neuron cells of a mammal (see, *e.g.*, page 18, lines 3 to page 19, line 20 and paragraph bridging pages 19 and 20) a neurotropic viral vector which infects cells of the central nervous system of the mammal (see, *e.g.*, paragraph bridging page 10 and 11 and page 15, lines 3-31), said vector containing a selected DNA sequence (see, *e.g.*, paragraph bridging page 9 and 10 and first paragraph of page 16) operatively linked to a selected promoter (see, *e.g.*, page 13, line 8 to page 9, line 35) so that said selected DNA sequence is stably expressed for at least four months by infected central nervous system cells. Further, the specification teaches the skilled artisan at least one use for the method of the invention (*i.e.*, to correct a deficiency in a biological function in cells of the central nervous system).

To comply with the enablement requirement, an applicant need not have actually reduced the invention to practice prior to filing. See MPEP 2164.02. The Courts have clearly held that "The mere fact that something has not previously been done clearly is

not, in itself, a sufficient basis for rejecting all applications purporting to disclose how to do it". 822 F.2d at 1078, 3 USPQ2d at 1304 (quoting *In re Chilowsky*, 229 F.2d 457, 461, 108 USPQ 321, 325 (CCPA 1956)). As the specification provides a sufficient description of all the elements necessary for how one of skill in the art can stably express a selected DNA sequence in the central nervous system and provides a working example to illustrate, Applicants believe that the instant specification has been improperly rejected on the basis of a reduction to practice for not showing a therapeutic benefit.

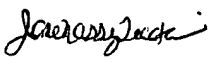
In an earnest effort to address the Examiner's concern regarding guidance for other vectors and promoters for use in methods of the invention, Applicants have amended claim 1 to indicate that the duration of expression recited in the claim is sustained using a LAT promoter. Because of this amendment, claim 2 has been canceled. At the time of filing, it was well-known in the art that neurotropic viruses such as rabies virus, HSV, BDV, HIV and HPV described in the present specification gain entry to the CNS via the peripheral nervous system and their use as vectors can be reasonably expected to deliver a selected DNA sequence to the CNS. Applicants believe that, independent of the viral vector used, there is a reasonable expectation of successfully sustaining stable expression of a selected DNA sequence for least four months in infected central nervous system cells using the LAT promoter because the LAT promoter drives transcription of transgenes using the cellular machinery of the host cell. Therefore, in view of the amendment to claim 1 and the teachings provided in the specification, Applicants believe that the instant specification

meets the enablement requirements of 35 U.S.C. §112, first paragraph. Withdrawal of this rejection is therefore respectfully requested.

II. Conclusion

Applicant believes that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,



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